

Massachusetts activity. Mylan, Inc. may be served by delivering a summons and copy of the complaint to its President, Robert J. Coury, at 781 Chestnut Ridge Road, Morgantown, WV 26505, or any other officer or managing agent at such address or to its agent for service of process, Corporation Service Company, 209 West Washington Street, Charleston, West Virginia 25302.

3. Defendant Mylan Pharmaceuticals, Inc., a subsidiary of Mylan, Inc., is a corporation organized and existing under the laws of the West Virginia with its principal place of business in West Virginia. Mylan Pharmaceuticals, Inc. regularly does business in Massachusetts and this lawsuit arises out of Mylan, Pharmaceutical Inc.'s Massachusetts activity. Mylan Pharmaceuticals, Inc., may be served by delivering a summons and copy of the complaint to its President, Harry A. Korman, at 781 Chestnut Ridge Road, Morgantown, WV 26505, or any other officer or managing agent at such address or to its agent for service of process, Corporation Service Company, 209 West Washington Street, Charleston, West Virginia 25302.

4. Defendant Mylan Technologies, Inc., a subsidiary of Mylan, Inc., is a corporation organized and existing under the laws of the State of West Virginia with its principal place of business in Vermont. Mylan Technologies, Inc. regularly does business in Massachusetts and this lawsuit arises out of Mylan Technologies, Inc.'s Massachusetts activity. Mylan Technologies, Inc., may be served with process by delivering a summons and copy of the complaint to its President, Carolyn Myers, at 1500 Corporate Drive, Suite 400, Cannonsburg, PA 15317, or any other officer or managing agent at such address or to its agent for service of process, Corporation Service Company, 209 West Washington Street, Charleston, West Virginia 25302.

JURISDICTION AND VENUE

5. Pursuant to 28 U.S.C. § 1332, this Court has jurisdiction over this case because it is a lawsuit between parties of diverse citizenship and the amount in controversy exceeds \$75,000. Venue is proper in this Court under 28 U.S.C. § 1391 because a substantial part of the events or omissions giving rise to the claim (i.e., Decedent's fentanyl overdose and resulting death) occurred in this district.

FACTS COMMON TO ALL COUNTS

6. This suit arises out of the wrongful death of Decedent as the direct and proximate result of the tortious and wrongful conduct of Defendants.

7. Decedent, in the exercise of due care and in conformity with her physician's instructions and recommendation applied a 100 mcg fentanyl patch prescribed to her for treatment of chronic pain. The patch she applied was a 100 mcg/hr Mylan fentanyl patch (the "Jameson Patch") and the patch caused her death from an overdose of fentanyl. The Jameson Patch worn by Decedent at the time of her death was designed, manufactured, marketed, and distributed by the Mylan Defendants.

8. At all relevant times, Mylan patches came in 25, 50, 75, and 100 mcg sizes. As referenced herein, the "Patch" shall refer to fentanyl transdermal system patches of any size unless specified otherwise. The Patch is a so-called "matrix" design patch containing the drug fentanyl. Fentanyl is an extremely dangerous drug that is at least 80 times more potent than morphine. Fentanyl is classified as a Schedule II controlled substance by the FDA and is only available by prescription and is generally indicated for the treatment of chronic pain.

9. The Patch is supposed to be applied by the patient or a caregiver to the body and delivers fentanyl through the patient's skin.

10. The Mylan Defendants design, manufacture, market, and sell the Patch and represent that it will release a specific amount of fentanyl into a patient at a specific rate, and thus produce a certain level of fentanyl in the blood of the patient depending on the dosage prescribed by a patient's physician.

11. The Mylan Defendants represented to doctors, including Decedent's prescribing physician, Michael Schrenko, M.D., that "*serum fentanyl concentrations are proportional to the fentanyl transdermal system delivery rate.*" The Mylan Defendants made that representation in the prescribing information for the Patch.

12. The Mylan Defendants design, manufacture, market, and sell its 100 mcg Patch, like the Jameson Patch, and claim that it will release fentanyl at a rate of 100 mcg per hour and produce a mean maximal blood fentanyl concentration of 2.5 ng/M.

13. The Mylan Defendants agree that a properly functioning 100 mcg Mylan fentanyl patch is designed to give a patient a mean maximal blood fentanyl concentration of 2.5 ng/ML.

14. The Mylan Defendants represented in the package insert for the Patch that a 100 mcg fentanyl patch would give patients a mean maximal fentanyl concentration of 2.5 ng/ML, as shown in Table A of the prescribing information for the Patch:

TABLE A
FENTANYL PHARMACOKINETIC PARAMETERS FOLLOWING FIRST 72 HOUR
APPLICATION OF A FENTANYL TRANSDERMAL SYSTEM

Dose	Mean (SD) Time to Maximal Concentration T_{max} (hr)	Mean (SD) Maximal Concentration C_{max} (ng/mL)
Fentanyl Transdermal System 12 mcg/hr	27.5 (9.6)	0.3 (0.2)
Fentanyl Transdermal System 25 mcg/hr	38.1 (18.0)	0.6 (0.3)
Fentanyl Transdermal System 50 mcg/hr	34.8 (15.4)	1.4 (0.5)
Fentanyl Transdermal System 75 mcg/hr	33.5 (14.5)	1.7 (0.7)
Fentanyl Transdermal System 100 mcg/hr	36.8 (15.7)	2.5 (1.2)

15. If a Patch functions as intended and it is properly used, the patient should not receive a harmful dose of fentanyl.

16. Decedent never abused the Patch or used it inappropriately.

17. The Patch is unreasonably dangerous for its intended or reasonably foreseeable use because it can and does cause lethal levels of fentanyl in patients who use the patch in accord with the Patient Information sheet that accompanies the Patch and their physician's instructions.

18. Prior to the time the Jameson patch was manufactured and distributed, the Mylan defendants knew or should have known that numerous patients had received lethal doses of fentanyl while using the Patch as prescribed.

19. The Mylan Defendants knew or should have known that patients were receiving lethal fentanyl doses from proper use of the Patch because:

- a. The Mylan Defendants conducted internal studies indicating that patients had received lethal levels of fentanyl while properly using the Patch;
- b. Families of patients who died while using Mylan fentanyl patches filed wrongful death lawsuits against the Mylan Defendants alleging that patients had died with a lethal fentanyl blood concentration while properly using the Patch;
- c. The Mylan Defendants received information from the FDA's adverse event reporting system indicating that patients had received lethal fentanyl levels while using the Patch as prescribed;
- d. The Mylan Defendants received information from the World Health Organization indicating that patients had received lethal fentanyl levels while using the Patch as prescribed; and

- e. The Mylan Defendants received or had access to publically available autopsy reports indicating that patients had died from fentanyl overdoses with lethal blood fentanyl levels while using the Patch as prescribed.

20. Decedent was prescribed the Jameson Patch by Michael Schrenko, M.D. for pain. Decedent filled the prescription in August 2008. Decedent died on September 28, 2008.

21. Decedent received a lethal blood concentration of fentanyl—which caused her to die of a fentanyl overdose—while using the Jameson Patch as prescribed.

22. A toxicology test performed on Decedent's blood showed that Decedent's blood fentanyl was 10 ng/ML at the time of her death.

23. The Decedent's blood fentanyl concentration of 10 ng/ML was in the reported lethal range and is four times greater than the 2.5 ng/ML mean maximal fentanyl concentration that a properly functioning 100 mcg Mylan fentanyl patch is designed to deliver.

24. The forensic pathologist who performed the autopsy determined that Decedent died from the effects of fentanyl toxicity.

25. The defective condition of the Jameson Patch was a proximate cause of Decedent's fentanyl overdose and resulting death.

CAUSES OF ACTION

COUNT I

BREACH OF THE IMPLIED WARRANTY OF MERCHANTABILITY

26. Plaintiff re-alleges and incorporates by reference the consistent allegations in the preceding paragraphs

27. At all times material hereto, the Mylan Defendants were engaged in the business of designing, manufacturing, assembling, selling, marketing, promoting and/or supplying the Patch, including the Jameson Patch.

28. The Mylan Defendants warranted that the Patch was, among other things, fit for the ordinary purpose for which fentanyl patches are used.

29. The Jameson Patch was in a defective condition at the time it was designed, manufactured, sold, and/or marketed by the Mylan Defendants and at the time that it left the hands of the Mylan Defendants. The defective condition of the Jameson Patch rendered the Patch unreasonably dangerous for its intended or reasonably foreseeable use. Its defective condition was non-obvious to the ordinary expected user of the Patch.

30. Decedent was unaware of the defective condition of the Jameson Patch at the time she used the product in the manner and for the purpose it was intended. The defective condition was a direct and proximate cause of Decedent's death and the damages described herein.

31. The Jameson Patch was in the hands of the Mylan Defendants when the defect occurred. Further, the injury sustained by Decedent, fentanyl toxicity, was the precise kind of injury that a defective Patch can cause. The Jameson Patch reached Decedent without any substantial change in its condition and the defective condition of the Jameson Patch was not due to improper intermediate handling. Without limitation, the Jameson Patch was defective because it malfunctioned and did not perform as designed in that it delivered a lethal dose of fentanyl through the Decedent's skin, causing her death.

A. MANUFACTURING DEFECT

32. The Mylan Defendants breached the implied warranty of merchantability which attached to the Jameson Patch because it contained one or more of the following manufacturing defects: (1) a defect in the materials from which the Patch was manufactured; (2) a defect in the manner in which the Patch's component parts were formed and assembled; (3) foreign objects

contained in the Patch; (4) deterioration of the Patch prior to sale; and/or (5) a defect in the way in which the Patch was prepared and packaged.

33. These manufacturing defects made the Patch (1) dangerous to an extent beyond that which would be contemplated by a user possessing ordinary knowledge common to the community as to its characteristics and (2) unreasonably dangerous for normal use. The defective and unreasonably dangerous condition of the Jameson Patch existed at the time the Patch left the Mylan Defendants' hands.

34. Without limitation, the Jameson Patch was defective and unreasonably dangerous because it contained a manufacturing defect that caused the Patch to malfunction during normal use and not to perform as intended and designed.

35. The Jameson Patch was designed to give Decedent a mean maximal blood fentanyl level of 2.5 ng/ML.

36. The fentanyl concentration produced by a Mylan fentanyl patch is proportional to the fentanyl transdermal system delivery rate.

37. The Jameson Patch was a 100 mcg/hour Patch and was designed to deliver fentanyl at the rate of 100 mcg/hour.

38. The Jameson Patch malfunctioned during normal use, delivered fentanyl to Decedent at a faster rate and in greater concentration than it was designed to give, thereby delivering a fatal dose of fentanyl to Decedent.

39. As described in the medical literature, the average lethal blood fentanyl level is 8.3 ng/ML.

40. In giving Decedent a lethal blood fentanyl concentration of 10 ng/ML, the Jameson Patch failed to perform in the manner reasonably to be expected in light of its nature and intended function.

41. Decedent was using the Jameson Patch in the normal manner.

42. Secondary causes were not responsible for the fatal fentanyl level found in Decedent's blood.

43. The manufacturing defects in the Jameson Patch were a proximate cause of Decedent's death and the damages claimed herein.

44. The Jameson Patch was also defective and unreasonably dangerous because it contained one or more of the following manufacturing defects:

45. Without limitation, the Jameson Patch was defective because it contained a contaminant (e.g., a solvent, surfactant, and/or soap) that caused excess fentanyl delivery to Decedent.

46. The contaminant made the Jameson Patch unreasonably dangerous because it increased the permeability of Decedent's skin and resulted in too much fentanyl being delivered to Decedent in too short a period of time.

47. The Mylan Defendants' means and method of manufacturing are inadequate to prevent contaminants from becoming incorporated into the Patches they manufacture and their current testing methods are insufficient to prevent distribution of contaminated, dangerous Patches to the consuming public.

48. Without limitation, the Jameson Patch was defective because the fentanyl it contained became supersaturated because of exposure to heat during manufacturing, storage, or transit.

49. A patch containing supersaturated fentanyl is defective and unreasonably dangerous because it delivers too much fentanyl too quickly to the patient, thereby causing the patient to overdose.

50. The Mylan Defendants' means and methods of manufacture, storage and distribution are inadequate to prevent Patches containing supersaturated fentanyl from being released to the consuming public..

51. The Mylan Defendants' current testing methods are insufficient to detect Patches that have been superstaturated from exposure to heat before the supersaturated Patches are sold to consumers.

52. Without limitation, the Jameson Patch was defective because it contained polymorphs created during the manufacturing process.

53. Polymorphs, which are created during the manufacturing process, affect the melting point and solubility of the polymeric matrix in the Patch. The Jameson Patch was defective and unreasonably dangerous because polymorphs contained in the Patch caused the Patch to deliver a lethal dose of fentanyl from the Patch into Decedent's skin.

54. Without limitation, the adhesive of the Jameson Patch contained a defect that permitted delivery of fentanyl to too large an area of Decedent's skin from the adhesive on the patient's skin surrounding the Patch.

55. Without limitation, the Jameson Patch contained a defect that allowed the release of fentanyl into Decedent's collected sweat and/or transepidermal water loss, which caused too much fentanyl to be delivered to the Decedent, causing her death.

56. On information and belief, the Jameson Patch contained other manufacturing defects that will be identified during discovery in this lawsuit.

57. All or some of the manufacturing defects described above existed at the time the Jameson Patch left the Mylan Defendants' control.

58. Secondary causes were not responsible for the fatal fentanyl level found in Decedent's blood.

59. The manufacturing defects described above caused the Jameson Patch to deliver a fatal overdose of fentanyl to the Decedent, proximately causing her death and the damages claimed herein.

B. FAILURE TO WARN

60. The Mylan Defendants also breached their implied warranty of merchantability concerning the Jameson Patch because they failed to provide adequate warnings about the dangers associated with the normal and foreseeable uses of the Patch.

61. The Mylan Defendants had a superior knowledge of the risks associated with use of the Patch and, therefore, had a duty to warn Decedent and her doctor about the dangers associated with its normal and foreseeable uses. The Mylan Defendants are held to the standard of experts with respect to the risks and benefits of the use of their product.

62. Neither Decedent nor her doctor were aware of these dangers.

63. The Mylan Defendants knew or should have known that patients were receiving lethal fentanyl doses from proper use of the Patch because:

- a. The Mylan Defendants conducted internal studies (indicating that patients had received lethal levels of fentanyl while properly using the Patch);
- b. Families of patients who died while using Mylan fentanyl patches filed wrongful death lawsuits filed against the Mylan Defendants (alleging that

patients had died with a lethal fentanyl blood concentration while properly using the Patch);

- c. The Mylan Defendants received information from the FDA's adverse event reporting system indicating that patients had received lethal fentanyl levels while using the Patch as prescribed;
- d. The Mylan Defendants received information from the World Health Organization indicating that patients had received lethal fentanyl levels while using the Patch as prescribed; and
- e. The Mylan Defendants received or had access to publically available autopsy reports indicating that patients had died from fentanyl overdoses with lethal blood fentanyl levels while using the Patch as prescribed.

64. Without limitation, the Mylan Defendants failed to provide adequate warnings and/or instructions to Decedent's doctor regarding the following risks:

- a. The risk of death from the proper use of the Patch;
- b. The risk that patients would receive potentially lethal fentanyl levels—far exceeding the levels the Patch was designed to deliver—while properly using the Patch;
- c. The risk of death from fentanyl's narrow therapeutic index. There is a small interval between therapeutic and toxic fentanyl levels. The Mylan Defendants failed to provide sufficient warnings about the risks associated with fentanyl's narrow therapeutic index;
- d. The risk of potentially fatal fentanyl overdoses caused by defectively manufactured Patches; and

- e. The risk of patient fentanyl overdoses and deaths caused by the use of fentanyl with other drugs;

65. The Mylan Defendants failed to provide sufficient warnings or instructions about the dangers associated with normal and foreseeable uses of the Patch to Decedent's doctor.

66. The absence of adequate warnings or instructions rendered the Jameson Patch unreasonably dangerous.

67. The Mylan Defendants' failure to provide such adequate warnings or instructions to Decedent's doctor was a direct and proximate cause of Decedent's death and the damages claimed herein.

C. DESIGN DEFECT

68. The Mylan Defendants also breached their implied warranty of merchantability concerning the Jameson Patch because its design was inadequate, and rendered the Patch unreasonably dangerous, taking into considering all of the circumstances that existed at the time the product was placed into the stream of commerce, including, without limitation: (1) the environment in which the product was designed to be used; (2) the gravity of the danger posed by its design; (3) the likelihood that such danger would occur; (4) the availability of alternative designs and the feasibility of such alternatives; (5) any risks inherent in such alternative designs; and (6) the costs associated with such alternative designs as compared with the cost of the product as it was actually designed and produced.

69. Without limitation, the Jameson Patch was defectively designed because: (a) it lacked a rate control membrane or a laminated face adhesive layer; and/or (b) the Patch utilized fentanyl instead of buprenorphine as its active ingredient.

70. Because the Jameson Patch lacked a rate control membrane or a laminated face adhesive layer, its design was inadequate to protect Decedent from uncontrolled delivery of a lethal dose of fentanyl.

71. Because Fentanyl is an extremely dangerous drug that is 80 to 100 times more potent than morphine, the dangers posed by the Jameson Patch's design, which failed to protect patients against uncontrolled fentanyl delivery, were extremely grave.

72. Numerous patients have received lethal levels of fentanyl while using fentanyl patches as prescribed.

73. The Mylan Defendants could have provided a safer alternative design.

74. The Jameson Patch could have been made safer by using an alternative design that provided added protection against rapid, uncontrolled fentanyl delivery, including:

- a. The addition of a rate controlling membrane to the Patch to provide protection against rapid fentanyl delivery; or
- b. The addition of a laminated face adhesive layer to the Patch. A laminated face adhesive layer, like a rate control membrane, would have provided protection against rapid fentanyl delivery.

75. At the time that the Jameson Patch was manufactured and released by the Mylan Defendants into the stream of commerce, safer alternative designs, incorporating a rate control membrane or a laminated face adhesive layer to prevent the uncontrolled release of fentanyl into a patient's skin were technically feasible. Moreover, such safer alternative designs would have been commercially viable.

76. Without limitation, the Jameson Patch had a design defect because it delivered fentanyl, a drug with a narrow therapeutic index that can be lethal in small amounts, through a matrix patch that did not ensure that fentanyl is delivered to patients at the intended rate.

77. The Jameson Patch was also defective and unreasonably dangerous because it could have had substantially equivalent analgesic effect with the use of a different analgesic drug -- buprenorphine, which would have provided effective pain relief with a much lower risk of death than the Mylan Defendants' fentanyl patch.

78. At the time that the Jameson Patch was manufactured and released by the Mylan Defendants into the stream of commerce, a safer alternative design, utilizing a safer analgesic drug was technically feasible. Moreover, such safer alternative design would have been commercially viable

79. The safer alternative designs described above, among others, could have been used.

80. The safer alternative designs existed at the time the Jameson Patch was manufactured and they would not have substantially impaired the Patch's utility.

81. The safer alternative designs described above were economically and technologically feasible at the time the Jameson Patch left the control of Mylan Technologies, Inc. by the application of existing or reasonably achievable scientific knowledge.

82. The defective design of the Jameson Patch existed at the time the product left the Mylan Defendants' hands.

83. Secondary causes were not responsible for the fatal fentanyl level found in Decedent's blood.

84. The defective design of the Jameson Patch was a proximate cause of Decedent's death and the damages claimed herein.

D. FITNESS FOR ORDINARY PURPOSE

85. The Mylan Defendants also breached their implied warranty of merchantability concerning the Jameson Patch because it was unfit for the ordinary purpose for which fentanyl patches are used.

86. The ordinary purpose for which 100 mcg fentanyl patches are used is to relieve a patient's pain by delivery of a dose of 100 mcg/hour of fentanyl over 72 hours, providing patients a with a mean fentanyl concentration of 2.5 ng/ML of blood.

87. The Jameson Patch malfunctioned and gave Decedent a lethal blood fentanyl concentration of 10 ng/ML while Decedent was using the Patch for its intended or reasonably foreseeable purpose. Therefore, the Jameson Patch was unfit for the ordinary purpose for which 100 mcg fentanyl patches are used.

88. The Jameson Patch's lack of fitness for its ordinary purpose was a proximate cause of Decedent's death and the damages claimed herein.

**COUNT II
NEGLIGENCE**

89. Plaintiff re-alleges and incorporates by reference the consistent allegations in the preceding paragraphs.

90. The Mylan Defendants had a duty to exercise reasonable care in the design, manufacture, marketing, testing, approval, application for approval, inspection, sale and distribution of the Patch into the stream of commerce.

91. The Mylan Defendants failed to exercise ordinary care in the design, manufacture, marketing, testing, approval, application for approval, inspection, sale, quality assurance,

reporting to the FDA, quality control and/or distribution of the Jameson Patch into interstate commerce and thus the Mylan Defendants were negligent in all of these areas.

A. NEGLIGENCE MANUFACTURING, TESTING, AND INSPECTION

92. The Mylan Defendants owed a duty to Decedent and other foreseeable users of their Patches to use reasonable care to prevent injury or death.

93. As a result of the Mylan Defendants' failure to exercise reasonable care in the manufacture, testing, or inspection of the Jameson Patch, it was placed in the stream of commerce in a dangerous and defective condition. The defective condition of the Jameson Patch was a direct and proximate cause of Decedent's fentanyl overdose and resulting death.

94. The Mylan Defendants' duty to use reasonable care in the manufacture of its product included the duty to make reasonable tests and inspections to discover latent or hidden defects or hazards in the product. The Mylan Defendants failed to perform such reasonable tests and inspections considering:

- a. The high degree of risk of patient overdose and/or death if the Patch failed. Fentanyl is an extremely dangerous drug that is 80 to 100 times stronger than morphine. If a Patch malfunctions and delivers too much fentanyl to a patient, it can cause a fatal fentanyl overdose.
- b. The significant likelihood of the existence of hidden defects in the Patch, including, without limitation:
 1. Contaminants (e.g., solvents, surfactants, and/or soaps) that cause the Patch to give excess fentanyl delivery to patients. The Mylan Defendants have a history of producing Patches with contaminants.

2. Supersaturation of the Patch's drug adhesive (due to exposure to heat during manufacturing, storage, or transit), which caused the Patch to deliver too much fentanyl to patients. Supersaturation from heat is a common occurrence with the Patch, which occurs during manufacturing, storage, or transit.
 3. Polymorphs created during the manufacturing process. Polymorphs affect the melting point and solubility of the polymeric matrix in the Patch. The presence of polymorphs increase the driving force of the fentanyl from the Patch into a patient's skin and cause the Patch to give a patient too much fentanyl.
 4. Defects in the adhesive of the Patch that permit delivery of fentanyl to too large an area of a patient's skin from the adhesive on the patient's skin surrounding the Patch.
 5. Defects in the Patch that allow the release of fentanyl into a patient's collected sweat and/or transepidermal water loss, which causes too much fentanyl to be delivered to the patient.
 6. Other manufacturing defects that will be identified during discovery in this lawsuit.
- c. Patches with the above-described defects could have be prevented from being released to patients if the Mylan Defendants had performed reasonable tests and inspections. Such reasonable tests and inspections

could have been made using available testing devices, facilities, and methods.

95. The Mylan Defendants failed to use reasonable care in the manufacturing, testing, and inspection of the Jameson Patch. Therefore, the Jameson Patch contained one or more of the above-described manufacturing defects.

96. The defective condition of the Jameson Patch caused the Patch to malfunction and give Decedent a fatal dose of fentanyl.

97. The negligent conduct of the Mylan Defendants, as alleged above, was a direct and proximate cause of Decedent's death and the damages described herein.

B. NEGLIGENCE DESIGN

98. The Mylan Defendants owed a duty to Decedent and other persons who they knew, or should have known, would use the Patch, to use reasonable care to design the Patch so as to make it reasonably safe for its intended use.

99. The Mylan Defendants could have reasonably foreseen that the design of the Patch exposed Decedent and other patients to the danger of fentanyl overdoses and death because: (a) it lacked a rate control membrane or a laminated face adhesive layer; and/or (b) it utilized fentanyl instead of buprenorphine.

100. The Jameson Patch was supposed to deliver 100 mcg/hour of fentanyl and to give Decedent a 2.5 ng/mL fentanyl concentration.

101. Because the Jameson Patch lacked a rate control membrane or a laminated face adhesive layer (to protect Decedent against uncontrolled drug delivery), the Jameson Patch malfunctioned and gave Decedent a lethal blood fentanyl concentration of 10 ng/mL.

102. The dangers posed by the Jameson Patch's design, which failed to protect patients against uncontrolled fentanyl delivery, were extremely grave.

103. The Mylan Defendants could have reduced the danger of patient overdoses by adding protection against rapid, uncontrolled fentanyl delivery, including:

- a. The addition of a rate controlling membrane to the Patch to provide protection against rapid fentanyl delivery. The Jameson Patch lacked a rate control membrane and therefore, provided less protection against rapid fentanyl delivery than it would have provided had a rate control membrane been added; and
- b. The addition of a laminated face adhesive layer to the Patch. The laminated face adhesive layer, like a rate control membrane, would have provided protection against rapid fentanyl delivery. The Jameson Patch lacks a laminated face adhesive layer and therefore, provided less protection against rapid fentanyl delivery than it would have provided had a laminated face adhesive layer been added.

104. The Mylan Defendants could also have made the Patch safer by using an alternative design that utilized buprenorphine, a drug that provides effective pain relief with a much lower risk of death than fentanyl. Using buprenorphine instead of fentanyl in the Patch would have provided comparable pain relief without the risk of death associated with the delivering fentanyl through a matrix patch.

105. The safer alternative designs described above, among others, could have been used.

106. The safer alternative designs existed at the time the Jameson Patch was manufactured and would have minimized the danger of patient overdoses and deaths without unduly or unreasonably interfering with the Patch's function or unreasonably increasing its cost.

107. The Mylan Defendants' failure to use a safer alternative design, such as the alternative designs discussed above, was a breach of their duty of reasonable care to the foreseeable population of users of the Patch considering: (1) the hazard involved (patient overdoses and deaths); (2) the function that the Patch is intended to perform (give patients a therapeutic level of fentanyl and not a lethal level); and (3) and the feasibility of the alternative design from an engineering and an economic standpoint. Therefore, the Mylan Defendants' failure to use a safer design was negligent and they are liable for the damages resulting therefrom.

108. The defective design of the Jameson Patch caused the Patch to malfunction and give Decedent a fatal level of fentanyl instead of the therapeutic level it was supposed to give her.

109. The negligent design of the Jameson Patch was a direct and proximate cause of Decedent's fentanyl overdose, her resulting death, and the damages claimed herein.

C. NEGLIGENCE FAILURE TO WARN

110. The Mylan Defendants knew that its Patches could, under foreseeable circumstances, present dangers to Decedent and other foreseeable users of the Patch. Therefore, the Mylan Defendants had a duty to take reasonable care to provide warnings about the foreseeable dangers associated with using the Patch adequate to safeguard the health of the foreseeable population of consumers who would be exposed to the Patch.

111. The Mylan Defendants knew or should have known that patients were receiving lethal fentanyl doses from proper use of the Patch because:

- a. The Mylan Defendants conducted internal studies (indicating that patients had received lethal levels of fentanyl while properly using the Patch);
- b. Families of patients who died while using Mylan fentanyl patches filed wrongful death lawsuits filed against the Mylan Defendants (alleging that patients had died with a lethal fentanyl blood concentration while properly using the Patch);
- c. The Mylan Defendants received information from the FDA's adverse event reporting system indicating that patients had received lethal fentanyl levels while using the Patch as prescribed;
- d. The Mylan Defendants received information from the World Health Organization indicating that patients had received lethal fentanyl levels while using the Patch as prescribed; and
- e. The Mylan Defendants received or had access to publically available autopsy reports indicating that patients had died from fentanyl overdoses with lethal blood fentanyl levels while using the Patch as prescribed.

112. Without limitation, the Mylan Defendants failed to provide adequate warnings and/or instructions to Decedent's doctor regarding the following risks:

- a. The risk of death from the proper use of the Patch;
- b. The risk that patients would receive potentially lethal fentanyl levels—far exceeding the levels the Patch was designed to deliver—while properly using the Patch;

- c. The risk of death from fentanyl's narrow therapeutic index. There is a small interval between therapeutic and toxic fentanyl levels. The Mylan Defendants failed to provide sufficient warnings about the risks associated with fentanyl's narrow therapeutic index;
- d. The risk of potentially fatal fentanyl overdoses caused by defectively manufactured Patches; and
- e. The risk of patient fentanyl overdoses and deaths caused by the use of fentanyl with other drugs;

113. The Mylan Defendants failed to provide sufficient warnings or instructions about the foreseeable dangers associated with normal and foreseeable uses of the Patch to Decedent's doctor.

114. The Mylan Defendants' failure to provide such adequate warnings or instructions to Decedent's doctor was a direct and proximate cause of Decedent's death and the damages claimed herein.

COUNT III **NEGLIGENT MISREPRESENTATION**

115. Plaintiff re-alleges and incorporates by reference the consistent allegations in the preceding paragraphs.

116. The Mylan Defendants knew or should have known in the exercise of reasonable care that the Patch created a high risk of unreasonable, dangerous side effects, including that proper use of the Patch can cause death. Despite this knowledge, the Mylan Defendants failed to communicate to the FDA, Decedent, physicians, distributors, pharmacists, and/or the general public, that proper use of the Patch could cause serious injury and/or death.

117. Instead, the Mylan Defendants represented to all such persons/entities that the Patch was safe when used as directed. Specifically, the Mylan Defendants' negligently represented that the Patch would produce a maximum fentanyl blood concentration that was much lower than the fentanyl concentration found in Decedent's blood at the time of her death, a representation that the Patch was safe for use, and a representation that the Patch can be used with other medications.

118. These representations were known to be, or in the exercise of reasonable care, should have been known to be false and misleading in that:

- a. The Mylan Defendants failed to provide true and accurate information, warnings and instructions as set forth herein;
- b. The Mylan Defendants, individually, and through their agents, representatives, distributors and/or employees, negligently misrepresented material facts about the Patch in the course of their business in that they made such misrepresentations when they knew or reasonably should have known of the falsity of such misrepresentations. Alternatively, the Mylan Defendants made such misrepresentations without exercising reasonable care to ascertain the accuracy of these representations;

119. The above misrepresentations were made to the FDA, Decedent, physicians, pharmacists, as well as the general public.

120. The Mylan Defendants intended to induce others to rely on their representations, including, without limitation, Decedent, her physicians, and pharmacists.

121. Decedent and others, including, without limitation, Decedent's physician(s) and her pharmacist(s), justifiably relied on the Mylan Defendants' misrepresentations.

122. Decedent's death and the damages alleged herein were the directly and proximately caused as a result thereof.

WILLFUL, WANTON, AND RECKLESS CONDUCT

123. The conduct of the Mylan Defendants as described herein was malicious, willful, wanton or reckless or was grossly negligent.

124. Such conduct was the direct and proximate cause of or substantially contributed to Decedent's death.

REQUEST FOR RELIEF

WHEREFORE, the Plaintiff Walter Jameson ("Plaintiff"), individually and as Personal Representative of the Estate of Deborah Jameson respectfully prays that:

- a. judgment enter against the defendants, Mylan, Inc., Mylan Pharmaceuticals, Inc., and Mylan Technologies, Inc. jointly and severally on all counts of this Complaint;
- b. the plaintiff be awarded in behalf of the heirs-at-law of Deborah Jameson full, fair and complete compensation under M.G.L. c. 229, § 2 for decedent's wrongful death and the economic and intangible injuries resulting therefrom to the heirs-at-law;
- c. the plaintiff be awarded in behalf of The Estate of Deborah Jameson full, fair and complete compensation under M.G.L. c. 229, § 6 for decedent's conscious pain and suffering;
- d. the plaintiff be awarded appropriate, independent and substantial punitive damages against the defendants as a consequence of their gross negligence which proximately caused or substantially contributed to the death of Deborah Jameson;
- e. the plaintiff be awarded, in behalf of each heir-at-law, full compensation for the loss of companionship and society suffered by the said heirs;
- f. the plaintiff be awarded all appropriate costs, attorneys' fees, expenses and pre and post judgment interest authorized by law on the judgments which enter in his behalf; and

g. the Court enter such other relief as is deemed just and appropriate.

JURY DEMAND

Plaintiff hereby demands a jury trial on all issues so triable.

WALTER JAMESON, individually and as
he is the duly appointed Personal
Representative of the Estate of DEBORAH
JAMESON, by his attorneys,

/s/ Michael D. Lurie

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